



Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

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PROPOSED REGISTRATION DECISION

Cellulose From Powdered Corn Cobs

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FOREWORD

Proposed Registration Decision for Cellulose From Powdered Corn Cobs

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing full registration for the sale and use of the technical grade active ingredient cellulose from powdered corn cobs and the end-use products Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice to control rats and mice indoors where no alternative food sources are available.

Current scientific data from the applicant, scientific reports and information from other regulatory agencies were evaluated to determine if, under the proposed conditions of use, the end-use product has value and does not present an unacceptable risk to human health or the environment.

This Proposed Registration Decision is a consultation document¹ that summarizes the science evaluation for cellulose from powdered corn cobs and the reasons for the decision. It also describes risk-reduction measures that will be required to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessment of cellulose from powdered corn cobs.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

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OVERVIEW

Proposed Registration Decision for Cellulose From Powdered Corn Cobs

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing full registration for the sale and use of the technical grade active ingredient cellulose from powdered corn cobs and the end-use products Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice to control rats and mice indoors where food sources can be removed.

An evaluation of available scientific information found that, under the approved conditions of use, the end-use product has value and does not present an unacceptable risk to human health or the environment.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration². The Act also requires that products have value³ when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g., children) as well as organisms in the environment (e.g., those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

² "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

³ "Value" as defined by Subsection 2(1) of the *Pest Control Products Act*: "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

Before making a registration decision on cellulose from powdered corn cobs, the PMRA will consider all comments received from the public in response to this consultation document⁴. The PMRA will then publish a Registration Decision Document⁵ on cellulose from powdered corn cobs, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation section of this consultation document.

What Is Cellulose From Powdered Corn Cobs?

Cellulose from powdered corn cobs is a rodenticide applied inside buildings to control rats or mice. The mode of action for cellulose from powdered corn cobs is not clear, but it appears to interfere with the digestive system by causing blockages in the intestine and cecum, resulting in dehydration and eventually death. In order to be effective, all other potential food sources must be removed from the treatment location.

❖ Health Considerations

◆ Can Approved Uses of Cellulose From Powdered Corn Cobs Affect Human Health?

Cellulose from powdered corn cobs is unlikely to affect your health when used according to the label directions.

Potential exposure to cellulose from powdered corn cobs is likely when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The anticipated levels used to assess quantitative and qualitative risks are established to protect the most sensitive human population (e.g., children and nursing mothers). Only uses for which the exposure is expected to be well below levels that cause no anticipated effects in animal testing are considered acceptable for registration.

The technical grade active ingredient cellulose from powdered corn cobs and the end-use products Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice are not expected to cause any significant toxicological effect on exposure in an acute situation. The publically available information suggests that cellulose from powdered corn cobs is not expected to exhibit chronic, developmental, reproductive or nervous system toxicity. This information also suggests that the cellulose from powdered corn cobs is unlikely to be classified as a carcinogen or as a genotoxicant.

⁴ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

⁵ "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

◆ **Residues in Water and Food**

Dietary risks from food and water are not of concern.

The use of the rodenticides is limited to non-food/feed situations. It is not anticipated that the use of Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice will result in dietary risk from food and/or water.

◆ **Risks in Residential and Other Non-Occupational Environments**

Non-occupational risks are not of concern provided that directions specified on the label are observed.

The risks in residential and non-occupational environments is likely confined to incidental contact with the rodenticides in a postapplication activity, such as discarding used rodenticide or bait station maintenance, and is considered negligible in the general population. Individuals with wheat sensitivities should avoid contact with Rode-trol Rodent Control Bait for Rats. The health risks to the majority of non-occupational bystanders are not of concern. Any health risks resulting from accidental oral ingestion of wheat in Rode-trol Rodent Control Bait for Rats by individuals, especially children, have been taken into account by the cautionary label statement on the primary display panel "Warning, contains the allergen wheat."

◆ **Occupational Risks From Handling Cellulose From Powdered Corn Cobs**

Occupational risks are not of concern when cellulose from powdered corn cobs is used according to the label directions.

Pesticide applicators loading and/or applying Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice may come in direct contact with cellulose from powdered corn cobs on the skin or through inhalation of loose cellulose material. The low toxicity of cellulose from powdered corn cobs and minimal anticipated exposure from Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice, both in pelletized form, suggests that occupational risk due to exposure is not expected to be a concern. The presence of wheat in Rode-trol Rodent Control Bait for Rats may be of concern for individuals with wheat sensitivities. The risk due to exposure to wheat has been taken into consideration by the cautionary label statement "Warning, contains the allergen wheat."

❖ Environmental Considerations

♦ What Happens When Cellulose from Powdered Corn Cobs Is Introduced Into the Environment?

Cellulose from powdered corn cob poses a negligible risk to the environment.

The Rode-trol products must be used as rodenticides indoors (i.e., buildings, warehouses, barns and empty feed storage areas); therefore, only negligible amounts will enter the environment. The powdered corn cob is a natural product composed primarily of plant carbohydrate material and is expected to readily break down in the environment.

Because the products are used indoors, there will be minimal environmental exposure of non-target species to the products. Target rodents that have consumed the products may travel outdoors. These products pose negligible risk to avian and mammalian predators and scavengers that may feed on dead or dying rodents.

❖ Value Considerations

♦ What Is the Value of Cellulose?

Cellulose is a rodenticide for control of rats and mice indoors (e.g., buildings, barns, empty feed storage areas, warehouses) where no other food sources are available.

Rode-trol LLC submitted an application to register Rode-Trol Rodent Control Technical Grade Active Ingredient (45% cellulose made from powdered corn cobs) as a rodenticide. The Rode-trol Technical is to be used in two end-use products Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice. Both products are to be applied in commercially available bait stations indoors where food sources can be removed. Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice are lower risk alternatives to conventional rodenticides used for the control of rats and mice indoors where no alternative food sources are available.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions are required by law to be followed.

Key risk-reduction measures on the label of Rode-trol Rodent Control Bait for Rats to address the potential risks identified in this assessment are limited to the following precautionary statement:

Key Risk-Reduction Measures

- **Human Health**

Rode-trol Rodent Control Bait for Rats contains the allergen wheat; therefore, there are concerns that individuals, particularly children, with sensitivities to wheat may experience an allergic reaction if Rode-trol Rodent Control Bait for Rats is accidentally ingested. A label statement identifying the presence of wheat is necessary for Rode-trol Rodent Control Bait for Rats.

No key risk-reduction measures are required for Rode-trol Rodent Control Bait for Mice.

Next Steps

Before making a registration decision on cellulose from powdered corn cobs, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Registration Decision Document, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and the Agency's response to these comments.

Other Information

At the time the PMRA makes its registration decision, it will publish an Evaluation Report on cellulose from powdered corn cobs (based on the Science Evaluation section of this consultation document). In addition, the test data on which the decision is based will also be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

SCIENCE EVALUATION

Cellulose From Powdered Corn Cobs

1.0 The Technical Grade Active Ingredient, Its Properties and Uses

1.1 Identity of the Technical Grade Active Ingredient

Active ingredient Cellulose from powdered corn cobs

Function Rodenticide

Chemical name

1. **International Union of Pure and Applied Chemistry (IUPAC)** Cellulose

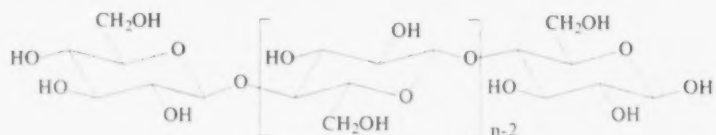
2. **Chemical Abstracts Service (CAS)** Cellulose

CAS number 9004-34-6

Molecular formula $(C_6H_{10}O_5)_n$

Molecular weight The molecular weight of the basic unit of cellulose is 162

Structural formula



Purity of the technical grade active ingredient 45.0% (limits: 43.65–46.35%)

1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Products

Technical Product—Rode-trol Rodent Control Bait Technical Grade Active Ingredient

Property	Result
Colour and physical state	Light brown, tan, solid
Odour	Faint, sweet odour
Melting range	Not applicable
Boiling point or range	Not applicable
Density	0.288–0.416 g/cm ³ at 20°C
Vapour pressure at 20°C	The product is a solid.
Henry's law constant at 20°C	The product is a solid.
Ultraviolet (UV)—visible spectrum	The active ingredient does not contain any UV absorbing moiety.
Solubility in water at 20°C	< 10% by volume
Solubility in organic solvents	Slightly soluble in acetone.
<i>n</i> -Octanol–water partition coefficient (K_{ow})	The active ingredient is not isolated from the technical grade active ingredient.
Dissociation constant (pK_a)	The product does not contain any dissociable moiety.
Stability (temperature, metal)	Expected to be stable.

End-Use Product—Rode-Trol Rodent Control Bait for Rats

Property	Result
Colour	Not provided
Odour	Not provided
Physical state	Solid
Formulation type	Pellets
Guarantee	42.3% (limits: 41.03–43.57%)
Container material and description	Polyethylene-lined paper bags, 10 and 20 kg
Density	0.288–0.416 g/cm ³ at 20°C
pH of 1% dispersion in water	Not applicable
Oxidizing or reducing action	The product has moderate reducing properties and no oxidizing properties.
Storage stability	Stable for two years.
Explosibility	The product does not contain any components with explosive properties.

End-Use Product—Rode-Trol Rodent Control Bait for Mice

Property	Result
Colour	Not provided
Odour	Not provided
Physical state	Solid
Formulation type	Pellets
Guarantee	42.75% (limits: 41.47–44.03%)
Container material and description	Polyethylene-lined paper bags, 10 and 20 kg
Density	0.288–0.416 g/cm ³ at 20°C
pH of 1% dispersion in water	Not applicable
Oxidizing or reducing action	The product has moderate reducing properties and no oxidizing properties.
Storage stability	Stable for two years.
Explosibility	The product does not contain any components with explosive properties.

1.3 Directions for Use

Rode-trol LLC has submitted an application to register Rode-trol Rodent Control Technical November 28, 2006 Grade Active Ingredient (45% cellulose made from powdered corn cobs) as a rodenticide. Rode-trol LLC has also applied for registration of two commercial class end-use products, Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice, containing the active ingredient cellulose.

Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice are to be used to control rats and mice indoors only (buildings, warehouses, barns and empty feed storage areas) where all potential food sources are removed. Both end-use products are to be applied in commercially available bait stations placed 1.2 to 1.8 metres apart, with each bait station containing 56.7 to 85 grams of bait. Bait stations must be inspected frequently and bait, replaced as it is consumed or if it is spoiled. An uninterrupted supply must be provided for a minimum of six to eight days or until signs of rat/mouse activity ceases for a period of two or more days.

1.4 Mode of Action

The mode of action for cellulose from powdered corn cobs is not entirely clear. The submitted studies indicate that cellulose interferes with the digestive system by causing blockages in the intestine and cecum, resulting in dehydration and eventually death. Rode-trol absorbs large quantities of water and takes significantly longer to break down compared to standard rodent food. In order to be effective, all other potential food sources must be removed from the treatment location.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Technical Grade of Active Ingredient

A gas chromatography method with flame ionization detector (GC-FID) was referenced for the analysis of monosaccharides present in the product. This is an official analytical method; therefore, the submission of the detailed method description and of the validation data have been waived.

2.2 Method for Formulation Analysis

A GC-FID method, which was referenced for the analysis of the active ingredient in the technical material, was also proposed for the analysis of the end-use products. It was assessed other formulants that are present in both proposed formulations may interfere with the analysis of cellulose. However, as these products are classified as low risk products, the submission of the enforcement analytical method has been waived.

2.3 Methods for Residue Analysis

The products are to be applied in non-food or feed situations. As such, residue analysis is not required.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

The PMRA conducted a review of the publically available toxicological information for cellulose from powdered corn cobs. In the absence of information dealing specifically with cellulose from powdered corn cobs, other cellulose material, such as microcrystalline cellulose and methyl cellulose, was used for this evaluation. The database is considered adequate to qualitatively assess the toxicity of this pest control product.

Refined cellulose is of low acute toxicity by the oral route in rats and microcrystalline cellulose is of low acute toxicity by the dermal and inhalation routes in rats. Cellulose was listed as non-irritating to minimally irritating in the publically available literature when applied to the skin and eyes of New Zealand white rabbits. Results listed in publically available information for skin sensitization testing in guinea pigs were negative. It is anticipated that these findings will reflect those of cellulose from powdered corn cobs.

The publically available acute and irritation information above will also be used to estimate the acute toxicity and irritation of both Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice. It is expected that the acute toxicity will be low for both end-use products, regardless of the route of exposure. Likewise, the eye and skin irritation is anticipated to be non-irritating to minimally irritating. It is also unlikely that either end-use products will be skin sensitizers. There is, however, the potential for an allergic reaction in sensitive individuals

exposed to Rode-trol Rodent Control Bait for Rats because the formulation contains wheat. Of particular concern are children who suffer from wheat allergies may ingest the pellets.

Absorption of repeated, non-lethal, oral doses of cellulose from powdered corn cobs was anticipated to be negligible and excretion nearly complete. Rats fed radiolabelled microcrystalline cellulose (10–20% of their diet) resulted in 96–104% recovery in the feces and none in the urine. The extent of metabolism of microcrystalline cellulose is also anticipated to be negligible, as per publically available information.

A short-term inhalation study exhibited an early inflammation response in the lungs of rats exposed to aerosols of cellulose, which peaked after the first day of exposure but declined thereafter.

An evaluation of available literature suggests that cellulose from powdered corn cobs is not expected to be a chronic, developmental, reproductive or nervous system toxicant, a carcinogen or a genotoxicant.

3.2 Determination of Acceptable Daily Intake

Application of cellulose from powdered corn cobs does not involve food or feed. Thus, a value for an acceptable daily intake was not necessary.

3.3 Determination of Acute Reference Dose

No significant acute effects were observed from the administration of a single dose of cellulose. Therefore, setting an acute reference dose was not necessary.

3.4 Occupational and Bystander Risk Assessment

3.4.1 Toxicological Endpoints

Occupational exposure to either Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice is expected to be short-term in duration and predominately by the dermal route when handled. Inhalation of loose material, consisting mainly of cellulose, is also possible but is likely to be a minor route of exposure. A 21-day inhalation study demonstrated early inflammation in the lung when exposed to a lowest observed adverse effect level (LOAEL) of 1000 fibres/mL. A no observed adverse effect level (NOAEL) could not be identified as only one concentration of cellulose fibre was tested. All other short-term testing was via the oral route and did not demonstrate any compound-related adverse effects. Although a margin of exposure could not be estimated with available information, it is not expected that exposure to the end-use products in pellet form will result in any significant potential for adverse effects.

The publically available information supports the position that cellulose from powdered corn cobs is unlikely to have any chronic, developmental, reproductive or nervous system toxicity as well as unlikely to be classified as a carcinogen or genotoxicant.

3.4.2 Dermal Absorption

Dermal absorption was not evaluated, but adequate protective statements are presented with the label to mitigate the need for such a study.

3.4.3 Mixer, Loader and Applicator Exposure and Risk Assessment

Pesticide applicators may be exposed to Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice by the dermal route when handling the rodenticide(s) in pellet form. There is also the potential for exposure by inhalation of any dust that may be generated from the pelletized product during shipping, storage and/or handling. It is expected that the majority of the loose material will be cellulose and, as the overall toxicity of both end-use products is very low, it is expected that exposure will not be a concern. Thus, exposure estimates for loaders or applicators were not evaluated either for Rode-trol Rodent Control Bait for Rats and for Rode-trol Rodent Control Bait for Mice.

There is also the potential for postapplication exposure from clean-up and maintenance of the bait stations. As with the loader and/or applicator exposure, an estimate was not performed because the products exhibit very low toxicity.

Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice are each applied at a maximum of 85 grams of end-use product per bait station, which is equivalent to 2.35 kilograms of active ingredient per day in a residential setting, assuming that an applicator treats 2 rooms per house, i.e., kitchen and pantry, and 5 houses in a typical 8-hour day. Bait stations should be placed at least 1.8 metres apart from one another.

3.4.4 Bystander Exposure and Risk Assessment

Bystander exposure is likely to be limited to inadvertent handling of the product after application by residents or others not involved in the loading, handling and/or application of the products. The low toxicity of Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice suggests that a bystander exposure and risk assessment was not necessary.

3.4.5 Food Residues Exposure Assessment

The products are to be used in non-food and/or non-feed situations. A food residue exposure assessment is not required.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

The technical grade active ingredient is composed of corn cobs ground into powder, containing the active ingredient cellulose. Corn cobs are the byproduct of corn grown as a food crop, and the stripped corn cobs have been used for many years for a variety of purposes including animal bedding, animal feed and fuel. Corn cobs are composed primarily of plant carbohydrate material

and will naturally break down in the environment. Major breakdown products include sugars, which are readily metabolized by microorganisms in the environment. The powdered corn cob is a natural product expected to break down in the environment and poses negligible environmental concern.

The products are proposed for indoor use (i.e., buildings, warehouses, barns and empty feed storage areas); thus, there will be negligible release of the products into the environment.

4.2 Effects on Non-Target Species

4.2.1 Effects on Terrestrial Organisms

Toxicity studies with Rode-trol Rodent Control Bait for Mice or Rat were conducted with eight non-target species to determine if they would consume bait when hungry and if toxic effects would result from consumption. Species tested included herbivorous mammals (guinea pig, rabbit, possum), carnivorous/omnivorous mammals (cat, dog, ferret) and birds (chicken, duck). Guinea pigs and rabbits consumed significant quantities of bait, but exhibited no signs of toxicity or dehydration, although bladders of some animals contained no urine. Cats and ferrets consumed negligible amounts of bait. Dogs and possums consumed bait on the first day of exposure, followed by negligible consumption thereafter; no signs of toxicity were noted, although some animals had low urine volume and/or dry feces. Ducks consumed significant quantities of bait, and chickens consumed low quantities of bait; neither bird showed any signs of toxicity, although some ducks had dry feces. Overall, tested species either consumed negligible amounts of bait or exhibited no toxic effects as a result of bait consumption. Although no signs of toxicity were observed, low urine volumes and dry feces were noted in some test animals; this is consistent with the high water absorptivity of cellulose, which can lead to adverse effects in some species. Toxicity study results are summarized in Appendix I, Table 3.

Based on the limited results from tested species, it appeared species that found Rode-trol highly palatable were able to consume the product with no adverse effects. These species included two herbivorous mammals (guinea pig, rabbit) and birds with significant plants/grains in their diet (duck), whose digestive systems may be better able to process the cellulose in Rode-trol. Other tested species did not find Rode-trol palatable and consumed only negligible or low amounts of the product despite being hungry, thereby experiencing no adverse effects. It is possible that they may have experienced adverse effects if they had consumed significant amounts of the product. It is also possible that non-target species closely related to rat and mouse may experience adverse effects should enough bait be consumed.

The end-use products, Rode-trol Rodent Control Bait for Mice or Rat, are for indoor use only (i.e., buildings, warehouses, barns and empty feed storage areas); thus, there will be minimal environmental exposure of non-target species to the products. Although used indoors, there is a low potential for accidental exposure of pets, farm animals or wild animals, either directly through consumption of the products or indirectly through consumption of dead or dying target rodents. Additionally, target rodents that have consumed the products may travel outdoors, increasing the possibility for exposure. Based on toxicity studies submitted, the risk to non-target birds and mammal species that may consume the products is expected to be negligible.

Furthermore, these products pose negligible risk of secondary poisoning to avian and mammalian predators and scavengers if they feed on target rodents that have eaten the products.

It is noted that some tested species (e.g., dog) generally did not find the product palatable. However, if they were to consume large amounts of the product, it is possible that they could experience adverse effects (such as constipation, intestinal blockage, etc.). Therefore, as a precautionary measure, the product should be kept away from all non-target animals, including pets.

4.2.2 Effects on Aquatic Organisms

The end-use products are proposed for indoor use only (i.e., buildings, warehouses, barns and empty feed storage areas), thus, there will be negligible exposure of aquatic organisms.

5.0 Value

5.1 Effectiveness Against Pests

Data from 22 efficacy trials conducted in the United States, United Kingdom, Singapore and New Zealand were submitted. Two publically available laboratory trials involving cellulose baits were also used during the efficacy assessment as supplemental information. Seven laboratory trials indicated that Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice will kill rats and mice when no alternative food sources are available. The remaining trials were conducted in various field locations (e.g., barns, warehouses, schools) and demonstrated a decline in the amount of bait consumed with time. However, these trials failed to demonstrate that the decline in bait consumption was a result of mortality in rats and mice caused by the bait or whether it was due to some other cause (e.g., palatability, migration).

The submitted efficacy data support the control of rats and mice indoors where no alternative food sources are present (i.e., buildings, warehouses, barns, feed storage areas) using Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice.

5.1.1 Acceptable Efficacy Claims

Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice are to be used to control rats and mice indoors only (buildings, warehouses, barns and empty feed storage areas). All potential food sources must be removed from the treatment area because the rats and mice must feed on the bait exclusively for a minimum of three days (mice) or eight days (rats) for the products to be effective. Both end-use products are to be applied in commercially available bait stations placed 1.2 to 1.8 metres apart with each bait station containing 56.7 to 85 grams of bait. Bait stations are to be inspected frequently with bait being replaced as it is consumed or if it is spoiled. An uninterrupted supply must be provided for a minimum of six to eight days or until signs of rat/mouse activity ceases for a period of two or more days.

Table 5.1.1.1 Acceptable Pests and Application Rates for Use of Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice

Product	Pest	Use sites	Application Rate	Remarks
Rode-trol Rodent Control Bait for Rats	Rats	Indoors (buildings, warehouses, barns and empty feed storage areas)	56.7–85 g of bait per bait station	Remove all food sources prior to treatment. Rats are sporadic feeders, so several bait stations are required. Place bait stations 1.2 to 1.8 m apart. Inspect bait stations every 48 hours and replace any eaten or spoiled bait. An uninterrupted supply of fresh bait should be available for at least 8 days or until signs of rat activity cease for a period of 2 or more days.
Rode-trol Rodent Control Bait for Mice	Mice	Indoors (buildings, warehouses, barns and empty feed storage areas)	56.7–85 g of bait per bait station	Mice are sporadic feeders, so several bait stations are required. Place bait stations 1.2 to 1.8 m apart. Inspect bait stations every 48 hours and replace bait any eaten or spoiled bait. Maintain an uninterrupted supply of fresh bait for at least 6–8 days or until signs of mouse activity cease for a period of 2 or more days.

5.2 Phytotoxicity to Host Plants

Not applicable.

5.3 Impact on Succeeding Crops

Not applicable.

5.4 Economics

Information was not provided.

5.5 Sustainability

5.5.1 Survey of Alternatives

Several active ingredients are registered to control rats and mice, including warfarin, zinc phosphate, sulfaquin oxaline, diphacinone, chlorophacinone, sulfur, bromadiolone, brodifacoum, 3-chloro-1-w-propanediol, cholecalciferol, bromethalin and difethialone. Non-chemical practices used to control rats and mice include traps, good sanitation, elimination of entry sites into buildings and removal of acceptable habitats.

5.5.2 Compatibility With Current Management Practices Including Integrated Pest Management

The end-use products Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice are capable of controlling rats and mice, respectively, when applied indoors where no alternative food sources are available. These products could be used in conjunction with current rat and mice control practices, such as good sanitation practices and removal of entry sites.

5.5.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Resistance by rats and mice to cellulose is unlikely. However, the sensitivity to cellulose may be dependent on the health of the rat or mouse and the availability of alternative food sources.

5.5.4 Contribution to Risk Reduction and Sustainability

Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice provide an alternative to conventional rodenticides used for the control of rats and mice indoors where no alternative food sources are available.

These end-use products are considered to be of low toxicity and exposure is expected to be limited to application and removal into and from the bait stations. As such, the overall risk to human health is anticipated to be extremely low.

The Rode-trol products containing cellulose from powdered corn cob pose significantly lower risk to the environment and to non-target species than conventional rodenticides, particularly the first and second generation anticoagulant rodenticides (i.e., products containing the active ingredients warfarin, brodifacoum, bromadiolone, chlorophacinone, diphacinone, difethialone). The anticoagulant rodenticides may be persistent and have the potential to bioaccumulate, whereas cellulose from powdered corn cob is a natural plant product that will not bioaccumulate and is expected to readily break down in the environment. Anticoagulant rodenticides are toxic to birds and mammals, whereas Rode-trol products containing cellulose from powdered corn cob exhibit negligible toxicity to tested bird and mammal species. The anticoagulant rodenticides may pose a risk of secondary poisoning to avian and mammalian predators and scavengers that consume target rodents or other prey items containing the anticoagulant residues (PACR2004-27, RRD2006-11, USEPA 1998, USEPA 2002). In contrast, the Rode-trol products containing cellulose from powdered corn cob pose negligible risk to avian and mammalian predators and scavengers that may feed on the dying or dead target rodents.

6.0 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's Toxic Substances Management Policy, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key

management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

During the review process, cellulose from powdered corn cobs was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with the use of cellulose from powdered corn cobs were also considered, including major transformation products formed in the environment, microcontaminants in the technical product and formulants in the end-use products Rode-trol Rodent Control Bait for Mice and Rode-trol Rodent Control Bait for Rat. The PMRA has reached the following conclusions:

- Cellulose from powdered corn cobs does not meet the Track 1 criteria. Cellulose from powdered corn cobs is a natural plant substance and is not expected to be persistent or bioaccumulative in the environment.
- Technical grade cellulose from powdered corn cobs does not contain any contaminants of health or environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.
- The end-use products, Rode-trol Rodent Control Bait for Mice and Rode-trol Rodent Control Bait for Rats, do not contain any formulants of health or environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.
- Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice are lower risk alternatives to conventional rodenticides and are to be applied in commercial bait stations. These products are to be used indoors where no alternative food sources are available.

Therefore, the use of cellulose from powdered corn cobs is not expected to result in the entry of Track 1 substances into the environment.

7.0 Summary

7.1 Human Health and Safety

The publically available information for cellulose from powdered corn cobs is adequate to qualitatively define the majority of toxic effects that may result from human exposure to cellulose from powdered corn cobs. In a short-term inhalation study on laboratory animals, transient inflammation in the lung was noted. No other toxicological effects were observed in any other publically available study for cellulose from powdered corn cobs.

Loader, applicators and workers entering treated structures are not expected to be exposed to levels of cellulose from powdered corn cobs that will result in unacceptable risk when Rode-trol Rodent Control Bait for Rats or Rode-trol Rodent Control Bait for Mice are used according to label directions. The precautionary statements on the product labels are adequate to protect workers, and no additional personal protective equipment is required.

Both Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice are not to be applied to any food or feed; thus, a maximum residue limit was not promulgated.

Supervision of children around the bait stations containing Rode-trol Rodent Control Bait for Rats is suggested, especially in cases where an individual is allergic to wheat. Accidental ingestion may result in an allergic reaction.

7.2 Environmental Risk

The Rode-trol products containing cellulose from powdered corn cobs are to be used indoors (i.e., buildings, warehouses, barns, and empty feed storage areas); therefore, only negligible amounts will enter the environment and there will be minimal exposure of non-target species to the product. Target rodents that have consumed the products may travel outdoors. These products pose negligible risk to avian and mammalian predators and scavengers that may feed on dead or dying target rodents.

7.3 Value

The data submitted to register Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice are adequate to describe its efficacy for use indoors (buildings, warehouses, barns and empty feed storage areas) where no alternative food sources are available. Mice and rats must feed on the bait exclusively for a minimum of three days or eight days, respectively. Both end-use products are to be applied in commercially available bait stations placed 1.2 to 1.8 metres apart, with each bait station containing 56.7–85 grams of bait. An uninterrupted supply must be provided for a minimum of six to eight days or until signs of rat and mouse activity ceases for a period of two or more days. These lower risk products are alternatives to conventional chemical rodenticides used to control rats and mice indoors.

7.4 Unsupported Uses

Certain uses originally proposed by the applicant with this application are not supported by the PMRA because value has not been adequately demonstrated. Unsupported uses are outlined in Appendix I, Table 5.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing full registration for the sale and use of the technical grade active ingredient cellulose from powdered corn cobs and the end-use products Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice to control rats and mice in non-food and/or feed related indoor structures.

An evaluation of current scientific data from the applicant, scientific reports and information from other regulatory agencies has resulted in the determination that, under the conditions of use, the end-use products have value and are not expected to present an unacceptable risk to human health or the environment.

List of Abbreviations

°C	degree Celsius
bw	body weight
CAS	chemical abstracts service
cm	centimetre(s)
DNA	deoxyribonucleic acid
g	gram
GC-FID	gas chromatography with flame ionization detector
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{ow}	<i>n</i> -octanol–water partition coefficient
L	litre
LC ₅₀	lethal concentration 50%
LD ₅₀	lethal dose 50%
LOAEL	lowest observed adverse effect level
mg	milligram
mL	millilitre
MAS	maximum average score
NOAEL	no observed adverse effect level
pK _a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet
WHO	World Health Organization

Appendix I Tables and Figures

Table 1 Acute Toxicity of Cellulose From Powdered Corn Cobs Technical (Rode-trol Rodent Control Bait Technical Grade Active Ingredient) and Its Associated End-Use Products (Rode-trol Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice)

Study Type	Species	Result	Comment
Acute Toxicity of Cellulose From Powdered Corn Cobs Technical			
Oral	Rat (♀)	LD ₅₀ > 2000 mg/kg bw	LOW TOXICITY Cellan 300 (refined α-cellulose) used for testing.
Dermal	Rat	LD ₅₀ > 2000 mg/kg bw	LOW TOXICITY Avicel RCN-15 (85% microcrystalline cellulose and 15% guar gum) used for testing.
Dermal	Rat	LD ₅₀ > 2000 mg/kg bw	LOW TOXICITY Avicel AC-815 (85% microcrystalline cellulose and 15% calcium alginate) used for testing.
Inhalation	Rat	LC ₅₀ > 5.35 mg/L	LOW TOXICITY Avicel AC-815 (85% microcrystalline cellulose and 15% calcium alginate) used for testing.
Skin irritation	Rabbit	MAS ^a = not reported	Non-irritating As per the WHO (1998).
Eye irritation	Rabbit	MAS = not reported	Minimally irritating As per the WHO (1998).
Skin sensitization (unknown test method)	Guinea pig	Negative	As per the WHO (1998).

Study Type	Species	Result	Comment
Acute Toxicity of End-Use Product—Rode-trol Rodent Control Bait for Rats			
N.B. Technical information used in lieu of acute studies for the end-use product.			
Oral	Rat (♀)	LD ₅₀ > 2000 mg/kg bw	LOW TOXICITY Cellan 300 (refined α-cellulose) used for testing.
Dermal	Rat	LD ₅₀ > 2000 mg/kg bw	LOW TOXICITY Avicel RCN-15 (85% microcrystalline cellulose and 15% guar gum) used for testing.
Dermal	Rat	LD ₅₀ > 2000 mg/kg bw	LOW TOXICITY Avicel AC-815 (85% microcrystalline cellulose and 15% calcium alginate) used for testing.
Inhalation	Rat	LC ₅₀ > 5.35 mg/L	LOW TOXICITY Avicel AC-815 (85% microcrystalline cellulose and 15% calcium alginate) used for testing.
Skin irritation	Rabbit	MAS ^a = not reported	Non-irritating As per the WHO (1998).
Eye irritation	Rabbit	MAS = not reported	Minimally irritating As per the WHO (1998).

Study Type	Species	Result	Comment
Acute Toxicity of End-Use Product—Rode-trol Rodent Control Bait for Mice			
N.B. Technical information used in lieu of acute studies for the end-use product.			
Oral	Rat (♀)	LD ₅₀ > 2000 mg/kg bw	LOW TOXICITY Cellan 300 (refined α-cellulose) used for testing.
Dermal	Rat	LD ₅₀ > 2000 mg/kg bw	LOW TOXICITY Avicel RCN-15 (85% microcrystalline cellulose and 15% guar gum) used for testing.
Dermal	Rat	LD ₅₀ > 2000 mg/kg bw	LOW TOXICITY Avicel AC-815 (85% microcrystalline cellulose and 15% calcium alginate) used for testing.
Inhalation	Rat	LC ₅₀ > 5.35 mg/L	LOW TOXICITY Avicel AC-815 (85% microcrystalline cellulose and 15% calcium alginate) used for testing.
Skin irritation	Rabbit	MAS ^a = not reported	Non-irritating As per the WHO (1998).
Eye irritation	Rabbit	MAS = not reported	Minimally irritating As per the WHO (1998).

^a MAS = maximum average score for 24, 28 and 72 hours

Table 2 Toxicity Profile of Technical Cellulose from Powdered Corn Cobs

Study Type	Species	Results ^a
21-day inhalation	Rat (♂)	NOAEL: not established LOAEL: 1000 fibres/mL (♂) Conversion from fibres/mL to mg/L was not possible with available information.
3-month dietary	Rat	NOAEL: not established LOAEL: > 3769 mg/kg bw/day (♂) and > 4446 mg/kg bw/day (♀)
2-year dietary	Rat	NOAEL: not established LOAEL: > 5% methyl cellulose in diet Conversion from percentage in diet to mg/kg bw/day was not possible with available information.
Developmental toxicity	Rat	Maternal NOAEL: not established Maternal LOAEL: > 4.5 g/kg bw/day Developmental NOAEL: not established Developmental LOAEL: > 4.5 g/kg bw/day
Reverse gene mutation assay (5 studies)	<i>Salmonella typhimurium</i>	Negative in 5 of 5 studies Avicel RCN-15 (85% microcrystalline cellulose and 15% guar gum) used for testing.
Reverse gene mutation assay (5 studies)	<i>Salmonella typhimurium</i> / <i>E.coli</i>	Negative in 5 of 5 studies Avicel AC-815 (85% microcrystalline cellulose and 15% calcium alginate) used for testing.
In vitro forward gene mutation	Mouse lymphoma L5178Y cells	Negative Avicel CL-611 (85% microcrystalline cellulose and 15% sodium carboxymethyl cellulose) used for testing.
In vitro forward gene mutation	Mouse lymphoma L5178Y cells	Negative Avicel RCN-15 (85% microcrystalline cellulose and 15% guar gum) used for testing.
In vitro unscheduled DNA synthesis	Primary rat hepatocytes	Negative Avicel RCN-15 (85% microcrystalline cellulose and 15% guar gum) used for testing.
In vivo mammalian cytogenetics	Mouse micronucleus assay	Negative Avicel RCN-15 (85% microcrystalline cellulose and 15% guar gum) used for testing.
In vivo mammalian cytogenetics	Mouse micronucleus assay	Negative Avicel CL-611 (85% microcrystalline cellulose and 15% sodium carboxymethyl cellulose) used for testing.

Study Type	Species	Results*
Metabolism	Rat	Absorption Approximately < 4% from the gastrointestinal tract at a dose of 10–20% of the diet. Rate of absorption anticipated to be negligible. Distribution Distribution is assumed to be negligible. Microcrystalline cellulose does not appear to have a potential to accumulate in the body. Excretion The majority of microcrystalline cellulose was recovered in the feces (96–104% of the administered dose) and no microcrystalline cellulose was found in the urine. Metabolism The rate of metabolism of microcrystalline cellulose appears to be negligible. It is expected that cellulose from powdered corn cobs will act in much the same manner as microcrystalline cellulose.

* Effects observed in males and females unless otherwise reported.

Table 3 Toxicity to Non-Target Species

Test Species	Test Substance	Sex n	Mean Body Weight (kg)	Bait consumption ^a	Mean Amount Consumed Over Total Exposure Period	Toxicity Results	Reference
Guinea pig (<i>Cavia porcellus</i>)	Rode-trol Rodent Control for Mice	F n = 5	0.526	5 consumed bait over 10 days	204 (144–293) g/kg bw (daily: 20 g/kg bw)	No signs of toxicity. Normal gross pathology. No signs of dehydration. 6/9 had no urine in the bladder.	PMRA 1071776
		M n = 5	0.665	4 consumed bait over 10 days	166 (192–233) g/kg bw (daily: 16 g/kg bw)		
Rabbit (<i>Oryctolagus cuniculus</i>)	Rode-trol Rodent Control for Rat	F n = 5	1.18	4 consumed bait over 10 days	77 (66–155) g/kg bw (daily: 7.7 g/kg bw)	No signs of toxicity. Normal gross pathology. No signs of dehydration. 5/9 had small volume of urine in the bladder. 1/9 had no urine in the bladder.	PMRA 1071777
		M n = 5	1.26	5 consumed bait over 10 days	93 (45–163) g/kg bw (daily: 9.3 g/kg bw)		
Cat (<i>Felis catus</i>)	Rode-trol Rodent Control for Mice	F n = 3	3.3	negligible consumption, all withdrawn after 3 days of refusal	0.7 (0.5–1.1) g/kg bw negligible consumption	No signs of toxicity. Cats refused bait for 3 consecutive days and were withdrawn from study. No gross pathology performed.	PMRA 1071780
		M n = 3	4.05	negligible consumption, all withdrawn after 3 days of refusal	0.3 (0.2–0.5) g/kg bw negligible consumption		
Dog (<i>Canis familiaris</i>)	Rode-trol Rodent Control for Rat	F n = 3	20.5	3 consumed bait on day 1, followed by negligible consumption	4.1 (1.0–9.2) g/kg bw (daily means: 0–3.8 g/kg bw)	No signs of toxicity. Normal gross pathology. One male had very dry feces.	PMRA 1071782
		M n = 3	25.1	3 consumed bait on day 1, followed by negligible consumption	5.7 (3.5–7.3) g/kg bw (daily means: 0–6.7 g/kg bw)		

Test Species	Test Substance	Sex n	Mean Body Weight (kg)	Bait consumption*	Mean Amount Consumed Over Total Exposure Period	Toxicity Results	Reference
Ferret (<i>Mustela furo</i>)	Rode-trol Rodent Control for Rat	F n = 3	0.853	negligible consumption, all withdrawn after 3 days of refusal	3.0 (0-4.9) g/kg bw negligible consumption	No signs of toxicity. Ferrets consumed negligible amounts or refused bait for 3 consecutive days and were withdrawn from study. No gross pathology performed.	PMRA/1071788
		M n = 3	0.92	negligible consumption, all withdrawn after 3 days of refusal	1.2 (0.7-1.5) g/kg bw negligible consumption		
Brush-tail Possum (<i>Trichosurus vulpeca</i>)	Rode-trol Rodent Control for Rat	F n = 5	3.38	5 consumed bait on day 1, followed by decreasing or negligible consumption	8.3 (1.4-15.4) g/kg bw (daily means: 0-6.3 g/kg bw)	No signs of toxicity. Normal gross pathology. No signs of dehydration. 3/6 had no urine in the bladder. Dry material in colon. 6/6.	PMRA 1071779
		M n = 5	3.59	5 consumed bait on day 1, followed by decreasing or negligible consumption	10.5 (2.8-17.3) g/kg bw (daily means: 0-4.3 g/kg bw)		
Mallard duck (<i>Anas platyrhynchos</i>)	Rode-trol Rodent Control for Mice	F n = 5	2.1	5 consumed bait over 3-7 days. (2 consumed negligible amounts)	22 (0.3-62) g/kg bw (daily means: 0-9.5 g/kg bw)	No signs of toxicity. Normal gross pathology. Some birds showed change in feces texture, became dry and crumbly on day 6 (normally wet).	PMRA 1071778
		M n = 5	2.48	5 consumed bait over 3-10 days	114 (7.1-255) g/kg bw (daily means: 0.2-25 g/kg bw)		
Chicken (<i>Gallus gallus</i>)	Rode-trol Rodent Control for Mice	F n = 5	1.71	5 low to moderate consumption in first 2 days, followed by no or negligible consumption	6.0 (0.4-22.4) g/kg bw (daily means: 0-5.4 g/kg bw)	No signs of toxicity. Normal gross pathology. Normal feces.	PMRA 1071781
		M n = 5	2.84	5 low to moderate consumption in first 2 days, followed by no or negligible consumption	10.9 (0.5-29.0) g/kg bw (daily means: 0-6.9 g/kg bw)		

* These studies were conducted to determine whether animals would consume bait and if toxic effects would result from consumption. Before the initial offering of bait, animals were deprived of food for 24 hours. During the exposure period (up to 10 days), hungry animals were offered bait in the morning as the only food choice and were offered a half-ration of regular diet approximately 5 hours later. Animals that refused bait for three consecutive days were withdrawn from the study.

Table 4 Alternative Rodenticides for the Control of Rats and Mice in Buildings

Active Ingredient	Pest	Locations of Use (refer to product labels for specific use directions)
Brodifacoum	Mice and rats	Industrial establishments; processing plants; food/feed establishments; farm buildings; dwellings; storage areas; transport vehicles (trains, planes, ships); empty granary bins
Bromadiolone	Mice and rats	Industrial establishments; storage areas; food/feed establishments; processing plants; farm buildings; dwellings; empty granary bins
Bromethalin	Rats	Industrial establishments; storage areas; food/feed establishments; farm buildings; dwellings
Cholecalciferol	Mice and rats	Industrial establishments; food/feed establishments; processing plants; storage areas; farm buildings; dwellings; empty granary bins
Chlorophacinone	Mice and rats	Industrial establishments; food/feed establishments; processing plants; farm buildings; dwellings; storage areas; empty granary bins
Difethialone	Rats	Industrial establishments; food/feed establishments; farm buildings; dwellings; food/feed/seed (stored)
Diphacinone	Mice and rats	Industrial establishments; food/feed establishments; farm buildings; dwellings; storage areas
Magnesium phosphide	Rats	Stored commodities (e.g., tobacco, food, feed)
Methyl bromide	Mice and rats	Industrial establishments; transport vehicles; various stored commodities (tobacco; Christmas trees; food, feed, fabric, wood and wood products); industrial establishments; processing plants; various stored commodities; grain elevators; food/feed establishments
Phosphine	Mice and rats	Industrial establishments; transport vehicles; stored commodities (e.g., tobacco; food, feed, seed; fabric, wood and wood products, leather, seed); empty greenhouses
Warfarin	Mice and rats	Industrial establishments; storage areas; food/feed establishments; processing plants; farm buildings; dwellings; empty granary bins
Warfarin and sulfaquinoxaline	Mice and rats	Food/feed establishments; processing plants; industrial establishments; storage areas; farm buildings; dwellings
Zinc phosphide	Mice and rats	Industrial establishments; farm buildings; storage areas; dwellings
3-chloro-1,2-propanediol	Rats	Processing plants; industrial establishments; storage areas; farm buildings; grain elevators

Table 5 Use Claims Proposed by Applicant and Whether Acceptable or Unsupported

Applicant-Proposed Label Claims	Accepted Label Claims	Unsupported Label Claims and Comments
Mode of Action The rodent digestive tract has a unique water absorption system regulated by a complex mechanism. Rode-trol [®] Rodent Control Bait for Rats and Rode-trol Rodent Control Bait for Mice physically disrupts the water absorption mechanism and the rodent becomes lethargic, falls into a coma and then dies.		The exact mode of action for cellulose remains unclear. However, the submitted data indicate that cellulose causes blockages in the digestive system.
Use Sites Indoor and outdoor use Buildings, warehouses, barns and feed storage areas Orchards, groves and vineyards Vegetables and strawberries	Indoor use Buildings, warehouses, barns and empty feed storage areas	Outdoor use Orchards, groves and vineyards Vegetables and strawberries
Application Methods Bait station Open-ended boxes or under a sheet of metal/wood placed at angle against a wall Burrow application Mechanical spreading Hand baiting Trail building	Bait Station	Open-ended boxes or under a sheet of metal/wood placed at angle against a wall Burrow application Mechanical spreading Hand baiting Trail building

References

A. List of Studies / Information Submitted by Registrant

2.0 Chemistry

- PMRA 909708 Chemistry Requirements, Rode-trol LLC, undated, 4 pages, DACO 3.2.2, 3.4.1 and 3.5.
- PMRA 910968 Chemistry Requirements, Rode-trol LLC, undated, 4 pages, DACO 3.2.2, 3.4.1 and 3.5.
- PMRA 1143714 Chemistry Requirements - Rode-Trol[®] Rodent Control Bait Technical Grade Active Ingredient - Tab 1, Rode-trol LLC, undated, 6 pages, DACO 2.11.2, 2.11.3, 2.13.3.
- PMRA 1143718 Journal of Chromatography A, 671 (1994) 339-350, 12 pages, Determination of Carbohydrates in Wood, Pulp and Process Liquor Samples by High-Performance Anion-Exchange Chromatography with Pulsed Amperometric Detection.
- PMRA 1143720 Technical Service Contract Report, Testing of Rode-Trol Products, Paprican Technical Service Contract Report TSC 048580, September 21, 2004, 3 pages, DACO 2.13.1.
- PMRA 1143721 JR Laboratories Inc., Analysis Certificate, Certificate ID: 7135, 04/07/28, 2 pages, DACO 2.16.

3.0 Impact on Human and Animal Health

- PMRA 910947 Request for waiver: toxicology, Rode-trol LLC, October 29, 2004, 2 pages, DACO 4.0.
- PMRA 910950 Comprehensive data summaries: cellulose, Rode-trol LLC, October 29, 2004, DACO 12.7.
- PMRA 909709 Request for waiver: toxicology, Rode-trol LLC, undated, 2 pages, DACO 4.0.
- PMRA 909712 Effects of orbis molasses pellet on rats when fed ad libitum, Delmar Company, sample orbis molasses pellet, Leberco Testing, Inc., Lab report number 9415100, October 11, 1994, 20 pages, DACO 4.6.1 and 4.8.

- PMRA 909711 The effect of the Delmar product pellets on *Rattus norvegicus* behaviour and mortality when fed predetermined amounts of product, Biological Control Products SA Ltd, no report number, September 14, 1994, 34 pages, DACO 4.8.
- PMRA 909713 Exposure (occupational and/or bystander) request for waiver, Rode-trol LLC, undated, 2 pages, DACO 5.0.
- PMRA 1071802 Use pattern/exposure studies: pellet, cellulose from powdered corn cob, Rode-trol LLC, undated, 7 pages, DACO 5.2.
- PMRA 910967 Toxicology - request for waiver, Rode-trol LLC, undated, 2 pages, DACO 4.0.
- PMRA 910976 Acute oral toxicity study, LD50 Delmar Company sample: orbis molasses pellet, September 14, 1994, 21 pages, DACO 4.6.1.
- PMRA 910977 Request for waiver: exposure-pellet-mice, Rode-trol LLC, undated, 2 pages, DACO 5.0.
- PMRA 1071775 Use pattern/exposure studies: Eradimouse, Rode-trol LLC, September 7, 2005, 6 pages, DACO 5.2.

4.0 Impact on the Environment

- PMRA 1071776 Susceptibility of the guinea pig (*Cavia porcellus*) to Eradimouse. Landcare Research. Landcare Research Contract Report: LC0203/117. Study Report Date: June 2003. 15 pages. DACO 9.9.
- PMRA 1071777 Susceptibility of the European rabbit (*Oryctolagus cuniculus cuniculus*) to Eradirat. Landcare Research. Landcare Research Contract Report: LC0203/116. Study Report Date: June 2003. 14 pages. DACO 9.9.
- PMRA 1071778 Susceptibility of the duck (*Anas platyrhynchos*) to Eradimouse. Landcare Research. Landcare Research Contract Report: LC0203/122. Study Report Date: June 2003. 15 pages. DACO 9.9.
- PMRA 1071779 Susceptibility of the brush-tail possum (*Trichosurus vulpecula*) to Eradirat. Landcare Research. Landcare Research Contract Report: LC0203/115. Study Report Date: June 2003. 18 pages. DACO 9.9.
- PMRA 1071780 Susceptibility of the cat (*Felis catus*) to Eradirat. Landcare Research. Landcare Research Contract Report: LC0203/118. Study Report Date: June 2003. 11 pages. DACO 9.9.

- PMRA 1071782 Susceptibility of the dog (*Canis familiaris*) to Eradirat. Landcare Research. Landcare Research Contract Report: LC0203/119. Study Report Date: June 2003. 14 pages. DACO 9.9.
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- PMRA 909719 Natrocell Technologies Limited Field Trials - The Orbis Molasses Pellet an all Natural & Organic Rodenticide to Control Rats and Mice -Trial No. 2. Natrocell Technologies Limited. Study report date: 13-December-1995. 19 pages. DACO 10.2.3.4.
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- PMRA 909724 The use of Eradirat in the control of the Brown rat (*Rattus norvegicus*) in an urban environment. Pest Management Consultants. Study report date: 2001. 19 pages. DACO 10.2.3.4.
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- PMRA 909726 Brief notes on the control of anticoagulant resistant rats (*Rattus norvegicus*). Pest Management Consultants. Study report date: 2000. 14 pages. DACO 10.2.3.4.
- PMRA 910982 Effects of Eradimouse on Mice When Fed Ad Libitum. Celsis Laboratory Group. Study No. GLP31754. Study report date: 07-October-2002 to 09-December-2002. 13 pages. DACO 10.2.3.2.
- PMRA 910983 Efficacy of Eradimouse against Feral House Mice. Landcare Research. Study No. LC0203/05. Study report date: December-2002. 16 pages. DACO 10.2.3.2.
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- PMRA 1071804 Request for Waiver of Food Choice Trial with preliminary results of food-choice trial from Biagro Technical Services. Rode-trol LLC Inc. 3 pages. DACO 10.2.3.2.
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B. Additional Information Considered

I) Published Information

2.0 Chemistry

None.

3.0 Impact on Human and Animal Health

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4.0 Impact on the Environment

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5.0 Value

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<http://bandwidthmarket.com/resources/patents/apps/2002/10/20020160031.html> Study report date: 31-October-2002. 15 pages.
Accessed by PMRA: 08-December-2005.

PMRA 1323121 Efficacy and palatability testing. Danish Pest Infestation Laboratory Annual Report 2001.
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II) List of Unpublished Information Considered

None.

